

## Consent Form

### *Instructions:*

- Complete the consent form based on the research protocol.
- The consent form must begin with a concise presentation of Key Information. Therefore, this consent form includes a section for Key Information and a section for Detailed Information.
  - Key Information should be limited, as prompted, to the information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
  - If the summary information in the Key Information section includes all relevant information for subjects, then delete the corresponding information from the Detailed Information section. If not, then provide the remaining non-summary information in the Detailed Section.
- Some items in this template are optional or based on certain types of studies (noted in red text). Review the guidance throughout the template.
- Refer to HRP-090 Informed Consent Process for Research, and HRP-091 Written Documentation of Consent in the [HRPP Toolkit Library](#).
- For additional resources on drafting a consent form, consider the following:
  - [Plain Language Thesaurus for Health Communications](#)
  - [Clear Language and Design](#)
  - [MN Health Literacy](#)
  - [Readability calculator](#) (use Flesch-Kincaid score)
- Remove help text and instructions before submitting the consent form draft to the IRB.
- Research conducted at the Center for Magnetic Resonance Research (CMRR) must incorporate recommended text highlighted throughout this template.

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**Title of Research Study:** *[insert title of research study here with protocol number, if applicable]*

**Investigator Team Contact Information:** *[insert name of principal investigator]*

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Investigator Departmental Affiliation: Phone Number: Email Address:	Study Staff (if applicable): Phone Number: Email Address:
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*[Include if the investigator is also the participant's treating physician. Otherwise delete.]* Your doctor, who is also responsible for this research study, *[or, If your doctor is also the person responsible for this research study, please note that s/he...]* is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

**Supported By:** *[List all monetary and/or non-monetary support for this research.]* This research is supported by \_\_\_\_\_.

**Financial Interest Disclosure:** *[Include if there is a personal and/or institutional financial interest to disclose. Otherwise delete.]* The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

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### ***Key Information About This Research Study***

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form. [You should aim for the entire Key Information section to be no longer than three (3) pages once you have removed all instructions.]

#### **What is research?**

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

#### **Why am I being asked to take part in this research study?**

We are asking you to take part in this research study because \_\_\_\_\_. [Fill in the circumstance or condition that makes participants eligible for the research.]

#### **What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

#### **Why is this research being done?**

[Include brief descriptions of the following elements in this section. Each element should be no longer than two (2) sentences in easily understandable language. You may introduce technical terminology as needed later in this form.]

(1) Tell the participant the purpose of the research in terms that can be understood by people not in the medical field.

(2) Explain the background of the research problem/question.

(3) Explain any potential benefits to others.

(4) If the study involves an investigational drug and/or device, state this and specify that investigational means that the drug or device is not approved by the FDA or not approved for the indication under investigation (i.e. how it is being used in the study).]

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### How long will the research last?

We expect that you will be in this research study for \_\_\_\_\_ [insert as hours, days, months, weeks, years, until a certain event. Estimate of total participation time should be included as well as time spent in specific activities (e.g. physical exam will require approximately 30 minutes).].

### What will I need to do to participate?

You will be asked to \_\_\_\_\_ [include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

### Is there any way that being in this study could be bad for me?

[This beginning section of the consent form should identify the most important risks, e.g., similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study.]

[Include if there are additional risks described below. Otherwise delete.] More detailed information about the risks of this study can be found under ***“What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)”***

### Will being in this study help me in any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_. [First describe any direct benefits to the subject, then any possible benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_. [Describe any possible benefits to others. Monetary reimbursement for participation is not a benefit.]

[Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

[Include if there are additional benefits described below. Otherwise delete.] More detailed information about the benefits of this study can be found under ***“Will being in this study help me in any way? (Detailed Benefits)”***

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### What happens if I do not want to be in this research?

[Include if there are alternatives other than participating.]

[No Specific Alternatives: Include this statement]

There are no known alternatives, other than deciding not to participate in this research study.

[Specific Alternatives Available/Known: Include this statement]

You do not have to participate in this research. Instead of being in this research study, your choices may include: [List alternatives procedures. For student participant pools, describe alternatives for course credit.

For clinical trials, describe the options that you would normally offer a patient.

If applicable, include supportive care as an option.]

[Include for a clinical trial. Otherwise delete.] The important risks and possible benefits of these alternatives include: [Describe the important risks and potential benefits of the alternative procedures and courses of care.]

## Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

### How many people will be studied?

We expect about \_\_\_\_\_ people here will be in this research study out of \_\_\_\_\_ people in the entire study nationally [or internationally].

### What happens if I say “Yes, I want to be in this research”?

[In terms that can be understood by people not in the medical field, tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:

- A timeline description of the procedures that will be performed. If practical, prepare a timeline or schedule of procedures to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits.
- The drugs or biologics that will be given to the participant.
- All devices that will be used.
- All hospitalizations, outpatient visits and telephone or written follow-up.
- The length and duration of visits and procedures.
- If blood will be drawn, indicate the amount [in English units] and frequency.
- With whom the participant will interact.
- Where the research will be done.
- When the research will be done.
- List experimental procedures and therapies and identify them as experimental.
- How often procedures will be performed.
- What is being performed as part of the research study.
- What is being performed as part of standard care.
- Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the whole

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- genome or exome sequence of that specimen).
- When applicable, indicate that the participant will be asked to provide permission to be contacted for future research.
- When applicable, describe whether audio and/or video recording of any research activities will be done. Include whether an agreement to be recorded is required for participation or if it is optional.
- **<CMRR Research Only>** Specific CMRR procedures may include: Screening procedures, including testing procedures needed before participation in MRI (e.g. pregnancy testing, x-ray to determine location of shrapnel); MRI screening procedures and duration of scanning (e.g. remove all metallic objects, wear hospital gown, etc.); whether study specific positioners like bite bars will be used or additional devices will be placed to communicate with or monitor the subject (e.g. heart rate or respiration monitoring, headphones) or conduct imaging (endo coils, etc.); additional procedures subjects will be asked to perform in this study while in the MRI scanner (e.g. perform tasks while lying in the scanner); and procedures associated with completion of the study (e.g. completion of exit questionnaires, etc.).

[Include this statement for a clinical trial or other research that involves randomization. Otherwise delete.] The experimental treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental treatment you get. You will have a(n) \_\_\_\_\_ [equal / one in three /etc.] chance of being given either experimental treatment.

[For double-blinded research add] Neither you nor the study doctor will know which experimental treatment you are getting.

[For single blinded research add] You will not be told which experimental treatment you are getting, however your study doctor will know.

### What are my responsibilities if I take part in this research?

[Delete this section if the research is not a clinical trial.]

*If you take part in this research, you will be responsible for: [Describe any responsibilities of the participant.]*

### What happens if I say “Yes”, but I change my mind later?

You can leave the research study at any time. You can leave the research study at any time and no one will be upset by your decision.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research study, [Describe the adverse consequences.]

If you decide to leave the research study, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the participant, if any.]

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, [Insert as applicable] your academic standing as a student, or your present or future employment.

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[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, information about you that has already been collected may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. [Note: The consent document cannot give the participant the option of having data removed.] If you agree, this information will be handled the same as the information obtained for the research study. [Note: If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access the participant's medical record or other confidential records requiring the participant's consent for purposes related to the study. However, an investigator may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.]

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether participants will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a participant may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

### **What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)**

[If there are no risks in addition to what was included in the Key Information section above, then delete this section. Otherwise, describe in sufficient detail each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks of procedures may be presented in a table form.]

- Physical risks
- Side effects of drugs and devices
- Psychological risks
- Privacy & confidentiality risks
- Legal risks
- Social risks
- Economic risks
- Group or community risks
- **<CMRR Research Only>** If the research involves the use of CMRR, include the following language:

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

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**Claustrophobia:** The scanner is a long narrow tube that may cause some people to feel claustrophobic.

**Hearing Damage:** The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.

**Nerve Stimulation:** Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.

**Disruption of Devices:** Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.

**Heating of Devices:** The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

Distinguish between the risks presented by participation in the research and the risks associated with any procedures or clinical care that would occur as part of standard clinical care, regardless of participation in the research. Also, in general, do not include results of animal studies, unless there is no other known risk information and inclusion would aid with understanding.]

This research may hurt you in the following ways: \_\_\_\_\_.

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks, this research may hurt you in ways that are unknown. These might be minor or be severe as to cause death.



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**<CMRR Research Only>**

**Will I receive any imaging results after an MRI?**

**Choose one of the following options for this section of the form and delete the description and remaining options.**

**Imaging results will not be shared with the subject:**

The pictures created during this study are for research purposes only and are not intended to provide health care to you. The investigator in charge of this study has decided that results from your scan will not be shared with you or your physician.

**Potentially clinically important imaging results will be shared with subject:**

The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your pictures. The investigator { in charge of this study } will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

**Imaging results will be reviewed and results shared with subject and others (subject's physician, medical record):**

The pictures created during this study are for research purposes. However, a Radiologist trained in reading the pictures will review all pictures collected during this study and the investigator in charge of this study will share your results with you and your physician. The pictures may also be placed in your medical record.

**What do I need to know about reproductive health and/or sexual activity if I am in this study?**

[Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.]

**<CMRR Research Only>**

**If the study involves use of CMRR, include the following regarding pregnancy:** The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

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The procedures in this research are known to harm a pregnancy or fetus in the following ways:  
\_\_\_\_\_. [Omit the previous sentence if there are no known risks.]

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. [Omit the previous two sentences for research whose risk profile in pregnancy is well known.]

You should not be or become pregnant [include as applicable “or father a baby” and/or “breastfeed” and/or “donate eggs/sperm”] while on this research study. [If applicable, also include the amount of time a participant should wait after participation to become pregnant or father a child.]

[Include if applicable. Otherwise delete.] If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while participating in this research study or for \_\_\_\_\_ months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You might be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary. [Include if applicable. Otherwise delete.] [Insert sponsor name] may want to follow pregnancy outcomes in the event of a pregnancy. You or your partner’s permission will be obtained prior to seeking follow-up on any pregnancy outcomes.

[Include if participants are postmenopausal women. Otherwise delete.] If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for \_\_\_\_\_ months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary. [Include if applicable. Otherwise delete.] [Insert sponsor name] may want to follow pregnancy outcomes in the event of a pregnancy. You or your partner’s permission will be obtained prior to seeking follow-up on any pregnancy outcomes.

**<CMRR Research Only>**

**Will I know about any new information about the effects of MRIs on human health?**

**Choose one of the following two options for the Notification of Significant New Findings section and delete the other**

**Option 1: For field strengths above 3T (and selected 3T projects required to insert this language):**

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### Notification of Significant New Findings about the Effects of MRI on Human Health

Personnel in the Center for Magnetic Resonance Research (CMRR), the site where you are participating in MRI research, maintain a list of the names and contact information of all participants included in research at this facility. This information is required and will be used by CMRR to notify participants of significant new information about the effects of MR on human health that develop over the course of MRI research. Participant's identifying information is stored securely and it is maintained in a confidential manner by persons with oversight of research conducted at the CMRR.

*Option 2: Studies using 3T only should use the following recommended language:*

**<CMRR Research Only>**

### Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

### Will it cost me anything to participate in this research study?

[Include for research that will *NOT* result in any costs to the participants (e.g. no research related costs or standard of care costs). Otherwise delete.] Taking part in this research study will not lead to any costs to you.

[Include for research that may result in additional costs to the participants. Otherwise delete.] Taking part in this research study may lead to added costs to you. [Describe what these costs are beyond the costs directly related to participation in the research. It may be appropriate to identify additional costs that the subject may incur, examples include: loss of income when the subject takes time off from work to participate in the clinical investigation, transportation costs, copayments, etc. Because these issues may be complex, it may be appropriate to refer the subject to a knowledgeable financial counselor or reimbursement specialist to explain the costs and the insurance and reimbursement issues prior to signing the consent form.]

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

### Will being in this study help me in any way? (Detailed Benefits)

[Delete this entire section if there are no benefits in addition to what was included in the Key Information section above.]

[Include whether there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_. [Describe the potential benefits of participation. First describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the

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research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

**[Include for a clinical trial with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit and should be described in a later section.]**

### What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. **[Add to this list other organizations that may have access to the participants records such as the medical service providers (for clinical trials), US Department of Defense Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.]**

**[Include one of the following Mandated or permitted Reporter Language statements if applicable. In studies in which investigators are probing for or likely to elicit information about child or vulnerable adult abuse or neglect, the State of Minnesota requires or permits investigators to report such information to authorities.]** If we learn about current or ongoing child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

**Or**

An exception to our promise of confidentiality is when we in good faith are required or permitted by law or policy to report evidence of child [or vulnerable adult] abuse or neglect.

**Or**

We will not ask you about child [or vulnerable adult] abuse, but if you tell us about child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

**[Describe any other limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover drug use or other sensitive information (refer to Reportable Disease Rule for information about [Minnesota's communicable disease reporting rule](#)), explain that this information may be disclosed to appropriate authorities.]**

### Certificate of Confidentiality

**[Include the following statement if the research is being conducted under a Certificate of Confidentiality. Otherwise delete.]** To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA)

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when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

### Data or Specimens Collected

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements.] If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. **OR** Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.

### Genetic Information

[Include for research involving genetic information. Otherwise delete.] A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

[Include for research where the sponsor may pay for medical expenses of the participant.] If the sponsor

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pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) (PDF) requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices. For more information see [CT.Gov Guidance](#).] A description of this clinical trial will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

### Will I receive research test results?

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens,] *If clinically relevant research results will be shared with research participants, include the content located under "Yes." If clinically relevant research results WILL NOT be shared with research participants, only include the content under "No".*

#### YES

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found. If the investigators return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

#### NO

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

### Will anyone besides the study team be at my consent meeting?

[Depending on the nature of the research protocol, there may be consent observation by the Post

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Approval Review Program or other monitoring entity. Some studies also include a provision of a third-party observer, such as a bioethicist.] You may be asked by the study team for your permission for an auditor to observe your consent meeting (or a recording of your consent meeting [remove if not applicable]). Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting (or a recording of your consent meeting [remove if not applicable]) without your permission ahead of time.

### Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to <https://research.umn.edu/units/hrpp/research-participants/questions-concerns>. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

### Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

### Can I be removed from the research?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the participant may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

### What happens if I am injured while participating in this research?

[If the research involves the potential for injury, one of the following three statements regarding

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Version Date: <date>



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appropriate compensation for injury must be included, as indicated on the medical application form.]

### [Option 1 - Non-Sponsor Funded Compensation]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

### [Option 2 - Sponsor Funded Compensation]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

### [Option 3: If the preferred injury compensation language is unacceptable to the study sponsor, the following alternative language may be used.]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances or if you think you have suffered a research related injury let the study physicians know right away.

## Will I be compensated for my participation?

[Include if participants will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

### [Include if the study will utilize Greenphire ClinCard for compensating participants. Otherwise delete.]

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.



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The debit card system is administered by an outside company. The company, Greenphire, will be given your name and [if not applicable remove the SSN statement] social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

[Use the following language if the subject will be receiving appointment reminders and/or payment reminders or updates via text messaging or email via Greenphire.]

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds \$600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed \$600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

[Include for Department of Defense (DOD) research that targets military personnel where participants will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard clinical care will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

### Use of Identifiable Health Information

[Include if HIPAA Authorization is required. Otherwise delete this section.]

[If included, do not alter any of the following text, except as indicated.] We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without

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your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

### Optional Elements:

[Include for any optional elements of the research approved by the IRB. Otherwise delete.] The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes,  
I agree

No,  
I disagree

\_\_\_\_\_

\_\_\_\_\_

The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.

\_\_\_\_\_

\_\_\_\_\_

The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification.

\_\_\_\_\_

\_\_\_\_\_

The investigator may contact me in the future to see whether I am interested in participating in other research studies by <Name of Principal Investigator>

\_\_\_\_\_

\_\_\_\_\_

The investigator may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity.

\_\_\_\_\_

\_\_\_\_\_

I would like to receive reminders using Greenphire.

If yes, provide the following contact information:

Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

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*[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. Omit the signature page if there is no written documentation of consent.]*

### Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

### Signature Block for Witness:

#### WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

\_\_\_\_\_  
☐ Other (please specify):

\_\_\_\_\_  
My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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\_\_\_\_\_  
Signature of Witness to Consent Process

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Witnessing Consent Process

### **Signature Block for Adult Unable to Consent:**

Your signature documents your permission for the named participant to take part in this research.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Date